Docket No.: 043956- 0159

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 5,135,759
Patentee: L.A. Johnson
Issue Date: August 4, 1992

LETTER OF TRANSMITTAL OF APPLICATION FOR SECOND INTERIM EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156(d)(5) and 37 C.F.R. §1.790

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is (1) an application for extension of term of United States Patent 5,135,759 and (ii) a petition for extension of time under 37 C.F.R. § § 1.182 & 1.183 (courtesy copy provided by facsimile).

The contents of the application consists of various statements made by the undersigned counsel pursuant to 37 C.F.R. § 1.710 et seq. including EXHIBIT A.

The Commissioner is hereby authorized to charge payment for the application and petition and any additional fees associated with this communication (or credit any overpayment) to Deposit Account No. 502134. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Gail E. Poulos
Registration No. 36,327
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Beltsville, Maryland 20705-5131

Phone: 301-504-5302
Facsimile: 301-504-5060
Date: July 27, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent 5,135,759
Patentee: L.A. Johnson
Issue Date: August 4, 1992

SUBMISSION OF APPLICATION FOR SECOND INTERIM EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156(d)(5)

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is an application for a second extension of term of U.S. Patent 5,135,759 including:

Letter of transmittal of Application for Second Interim Extension of Patent term Under 35 U.S.C. § 156(d)(5).

Contents of the application made by applicant and counsel pursuant to 37 C.F.R. § 1.710 et seq. including Exhibit A.

(1) **A COMPLETE IDENTIFICATION OF THE PATENT FOR WHICH A SECOND INTERIM EXTENSION IS BEING SOUGHT:**

A complete identification of the patent is presented as follows:

Inventor:	Lawrence A. Johnson
Patent No.:	5,135,759
Issue Date:	August 4, 1992
Expiration Date:	August 4, 2009

(2) **A STATEMENT IN REGARDS TO THE REGULATORY REVIEW PERIOD**

The regulatory review period for the product which is used in the claims of U.S. Patent No. 5,135,759 has not been completed.

(3) **A STATEMENT OF THE RELEVANT DATES AND INFORMATION PURSUANT TO 35 U.S.C. § 156(g) IN ORDER TO ENABLE THE SECRETARY OF HEALTH AND HUMAN SERVICES TO DETERMINE THE ELIGIBILITY OF THE PATENT FOR A SECOND INTERIM PATENT TERM EXTENSION:**

Information and Dates Reported in Initial Interim Patent Term Extension:

Date of First Clinical Investigation:	1994
Date FDA requested GIVF submit an IDE:	Dec. 7, 1999
Date IDE filed:	April 24, 2000
IDE No.:	G000111
Date of Filing PMA Module 1 application:	March 31, 2008
The PMA (Module 1) Number:	M080005/M1
Date of Filing PMA Module 2:	July 22, 2008
The PMA (Module 2) Number:	M080005/M2
Date of Filing PMA Module 3:	March 31, 2009
PMA (Module 3) Number:	P090004

Relevant Information and Dates: Second Interim Patent Term Extension

Date of Continued Access Study Approval Grant	May 1, 2009
Date of Conditional Approval Grant of GIVF's fifth Continued Access Request	May 25, 2010
Date of Filing Request for Panel Meeting (PMA Amendment 7)	June 30, 2010

(4) A BRIEF DESCRIPTION OF THE SIGNIFICANT ACTIVITIES UNDERTAKEN BY THE MARKETING APPLICANT DURING THE APPLICABLE REGULATORY REVIEW PERIOD WITH RESPECT TO THE PRODUCT CURRENTLY UNDERGOING REGULATORY APPROVAL REVIEW AND THE SIGNIFICANT DATES APPLICABLE TO SUCH ACTIVITIES

Since filing the initial interim patent term extension application on June 8, 2009, the marketing applicant (GIVF) has provided the FDA with several supplements and amendments to the PMA in response to FDA inquiries and a request for further datasets. GIVF also provided the FDA its ninth and tenth annual IDE progress reports on July 1, 2009 and May 19, 2010, respectively.

On May 25, 2010, the FDA granted GIVF conditional approval of GIVF's fifth continued access request for genetic disease indication only and granted conditional approval of proposed revisions to the GIVF consent form and study protocol. GIVF has since appealed the FDA decision of 'genetic disease only' approval of its fifth continued access request and has submitted a response to the conditional approval of its fifth continued access request pertaining to a revised consent form and study protocol.

On June 30, 2010 GIVF submitted a request for a panel meeting for the MicroSort PMA.

GIVF believes that it has pursued its activities with due diligence throughout the continued regulatory review period. Significant activities undertaken by GIVF with respect to the MicroSort marketing application since filing the initial interim patent term extension on June 8, 2009 are briefly described as EXHIBIT A.

(5) **THE PRESCRIBED FEE FOR RECEIVING AND ACTING UPON THE APPLICATION FOR EXTENSION:**

Please charge the **Deposit Account 50-2134** (of USDA) in the amount of **$220.00** as the fee covering the instant application for interim patent term extension. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to **Account No. 50-2134**.

DECLARATION OF ATTORNEY

I hereby declare that all statements made herein of my own knowledge are true; that all statements on information and belief are believed to be true; that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application; that I am a patent attorney authorized to practice before the United States Patent and Trademark Office; I am an authorized designee of USDA for the purpose of submitting this application for interim patent term extension, and hence, have the authority to submit and prosecute this application on behalf of the Secretary of Agriculture; and that I have reviewed and understand the contents of this application being submitted; that I believe the subject patent is subject to interim extension pursuant to 37 C.F.R. § 1.710; and that I believe that the subject patent meets the conditions for term extension as set forth in 37 C.F.R. § 1.790.

Respectfully submitted,

Gail E. Poulos
Registration No. 36,327
USDA-ARS-OTT
5601 Sunnyside Avenue
Beltsville, Maryland 20705-5131

Phone: 301-504-5302
Facsimile: 301-504-5060
Date: July 27, 2010

Exhibit A

DATE	TO/FROM	SUBJECT
5/01/09	GIVF/FDA	GIVF receives email request for PMA datasets with line listings for each clinical site; GIVF receives email containing questions regarding the PMA.
5/04/09	FDA/GIVF	GIVF submits response to FDA request for case summary of a MicroSort baby described in GIVF's continued access request dated 4/6/09 (Supplement 54).
5/06/09	FDA/GIVF	Conference call to clarify questions raised by FDA in 5/01/09 email.
5/29/09	FDA/GIVF	GIVF submits a dataset with line listings requested by FDA (PMA Amendment 1).
6/16/09 – 6/30/09		BIMO site inspection of MicroSort-West.
6/23/09 - 6/30/09		BIMO site inspection of MicroSort Fairfax.
6/23/09 – 6/30/09		BIMO sponsor inspection of GIVF.
6/26/09	FDA/GIVF	GIVF submits response to questions raised by FDA in email dated 5/01/09 and during conference call on 5/06/09 (PMA Amendment 2).
7/01/09	FDA/GIVF	GIVF submits ninth annual IDE Progress Report (Supplement 56).
7/16/09	FDA/GIVF	GIVF submits response to MicroSort -West BIMO site inspection observations.
7/17/09	FDA/GIVF	GIVF submits response to GIVF BIMO sponsor inspection observations.
8/11/09	GIVF/FDA	GIVF receives PMA deficiency letter from FDA.
9/30/09	FDA/GIVF	GIVF submits request for extension of third continued access period until 12/1/09 (Supplement 57).

10/15/09	GIVF/FDA	FDA approves request for extension of third continued access period.
11/02/09	FDA/GIVF	GIVF submits fourth continued access request for expanded approval of GIVF's Continued Access Study with supporting additional information (Supplement 58).
11/02/09	GIVF/FDA	GIVF receives letter regarding BIMO inspection of MicroSort -West site.
11/10/09	GIVF/FDA	GIVF receives letter regarding BIMO sponsor inspection of GIVF.
11/11/09	FDA/GIVF	GIVF submits supplemental information requested by FDA regarding GIVF's fourth continued access request (Supplement 60).
11/20/09	FDA/GIVF	GIVF submits response to FDA letter for MicroSort -West site.
12/01/09	FDA/GIVF	GIVF submits additional supplemental information requested by FDA regarding GIVF's fourth continued access request (Supplement 60).
12/02/09	GIVF/FDA	Approval granted for Continued Access Study; made conditional on revisions to informed consent form; limited to enrollment of 50 new patients for three months.
12/17/09	FDA/GIVF	GIVF submits response to letter dated 11/10/09 (Supplement 62).
2/05/10	FDA/GIVF	GIVF submits request for 180 day extension of the period to respond to PMA deficiency letter (PMA Amendment 3).
2/20/10	GIVF/FDA	GIVF receives EIR and close-out letter in response to GIVF corrective action taken in response to letter of 11/02/09.
2/22/10	FDA/GIVF	GIVF submits response to all clinical and some non-clinical questions raised in PMA deficiency letter dated 8/02/09 (PMA Amendment 4).
2/24/10	GIVF/FDA	GIVF receives approval of extension of period to respond to PMA deficiency letter.
4/13/10	GIVF/FDA	GIVF receives EIR and close-out letter from FDA for letter dated 11/10/09.

4/28/10	FDA/GIVF	GIVF submits fifth continue access request for expanded approval of GIVF's Continued Access Study with supporting additional information (Supplement 66).
5/19/10	FDA/GIVF	GIVF submits tenth annual IDE Progress Report (Supplement 67).
5/25/10	GIVF/FDA	GIVF receives conditional approval for GIVF's fifth continued access request for genetic disease indication only and conditional approval of the revisions to the GIVF consent form and study protocol.
5/28/10	FDA/GIVF	GIVF submits responses to remaining non-clinical questions raised in PMA deficiency letter (PMA Amendment 5).
6/02/10	FDA/GIVF	GIVF submits appeal of FDA decision of 'genetic disease only' approval for GIVF's fifth continued access request (Supplement 68).
6/08/10	FDA/GIVF	GIVF submits a letter to FDA notifying FDA of GIVF permission to speak to Mr. Mark Heller and Ms. Christine Bump of Goodwin Procter regarding the MicroSort Study (PMA Amendment 6).
6/29/10	FDA/GIVF	GIVF submits response to FDA conditional approval letter for GIVF's fifth continued access request together with revised GIVF consent form and study protocol (Supplement 69).
6/30/10	FDA/GIVF	GIVF submits request for panel meeting for the MicroSort PMA (PMA Amendment 7).
7/08/10	FDA/GIVF	GIVF follows up its request for a panel meeting *via* email requesting that a panel meeting be scheduled.
7/09/10	GIVF/FDA	GIVF receives e-mail response from FDA informing that GIVF's request for a panel meeting for the PMA is under review.
7/14/10	GIVF/FDA	E-mail from FDA to GIVF requesting a timeline for completion of non-clinical testing (cytometer validation, laser spectral analysis, cytometer cleaning and disinfection validation) .
7/15/10	FDA/GIVF	GIVF sends letter as an e-mail attachment to FDA in response to FDA's 7/14/10 request for a timeline.

7/19/10	FDA/GIVF	GIVF sends a letter of appeal to FDA ombudsman David Buckles regarding FDA's failure to schedule a MicroSort PMA panel meeting.
7/20/10	FDA/GIVF	GIVF forwards a copy of the letter sent to FDA ombudsman dated 7/19/10 to Christy Forman at FDA.
7/20/10	FDA/GIVF	GIVF conducts a face-to-face meeting with FDA to present its appeal for approval of GIVF continued access for family balancing.
7/22/10	GIVF/FDA	BIMO sponsor follow-up inspection of GIVF.
7/23/10	FDA/GIVF	GIVF conducts telephone call with Michael Bailey at FDA to discuss changes to consent form for continued access for genetic disease indication.